



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-1018; FRL-9340-5]

#### Quizalofop Ethyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of quizalofop ethyl in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes established tolerances on canola seed and canola meal, as they will be superseded by new tolerances. Finally, this regulation removes several time-limited tolerances, as they have expired. Interregional Research Project Number 4 (IR-4) requested these tolerances, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-1018. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as

copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; e-mail address: [nollen.laura@epa.gov](mailto:nollen.laura@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not

listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines," which is listed under "Documents related to our mission."

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-1018 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-1018, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Summary of Petitioned-For Tolerances**

In the **Federal Register** of February 25, 2011 (76 FR 10584) (FRL-8863-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition, PP 0E7802, by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.441 be amended by establishing tolerances for residues of the herbicide quizalofop ethyl, ethyl-

2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate, including its metabolites and degradates, in or on rapeseed subgroup 20A, except flax, seed at 1.0 parts per million (ppm); gold of pleasure, meal at 1.5 ppm; crambe, meal at 1.5 ppm; sorghum, grain at 0.2 ppm; sorghum, forage at 0.2 ppm; sorghum, stover at 0.35 ppm; and sorghum, aspirated grain at 1.0 ppm. The petition additionally requested that EPA amend tolerances in 40 CFR 180.441 by removing the established tolerance for canola, seed at 1.0 ppm from the table in paragraph (a)(3), as the individual tolerance will be superseded by inclusion in rapeseed subgroup 20A, except flax, seed. The petition also proposed to remove the tolerances in §180.441(a)(4), as these tolerances expired on June 14, 1999.

The petition, PP 0E7802, also proposed to amend 40 CFR 180.441 by combining the tables for sections (a)(1) and (a)(3) into one table under section (a)(1), and by removing section (a)(3). It further proposed to revise the tolerance expression under section (a)(1). The petition, PP 0E7802, additionally proposed to revise the tolerance expression under section (a)(2).

Finally, PP 0E7802 proposed to revise the tolerance expression under section (c). That notice referenced a summary of the petition prepared on behalf of IR-4 by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has revised the proposed tolerance level and/or commodity definition for several commodities. The Agency has also removed the established tolerance on canola, meal, as the data were used

to establish a tolerance on rapeseed meal, the preferred commodity terminology. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for quizalofop ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with quizalofop ethyl follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to

human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Quizalofop ethyl has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or dermal irritant nor a skin sensitizer. The liver has been identified as the target organ, as evidenced by increased liver weights and histopathological changes in the liver. There were no effects observed in the oral toxicity studies that could be attributable to a single-dose exposure and no observed toxicity in a subchronic dermal toxicity study in rabbits. Following subchronic oral exposures, decreased body weight gains, increased liver weight and centrilobular liver cell enlargement were noted in rats, and an increased incidence of testicular atrophy was noted in dogs. A combined chronic toxicity/carcinogenicity study in rats noted an increased incidence of centrilobular enlargement of the liver in both sexes and mild anemia in males. No treatment-related effects on brain weight or histopathology of the nervous system were observed in studies that measured those endpoints.

In developmental toxicity studies in rats and rabbits, maternal effects, including decreased body weight gains and food consumption, were noted at a level that did not result in developmental effects. In the 2-generation reproduction study in rats, maternal effects including decreased body weight and body weight gains were noted at the same dose level that resulted in prenatal and postnatal effects (decreased percentage of pups born alive and decreased pup weights).

Carcinogenicity studies in rats and mice disclosed no more than very limited data suggestive of a potential for carcinogenic risk. No evidence of carcinogenicity was seen

in female mice and in male or female rats. Liver tumors were found in male mice. However, these tumors were seen only at an excessive dose, occurred at low incidence, showed marginal statistical significance at the high dose (no dose response), and were not accompanied with corroborative pre-neoplastic lesions. Further, liver tumors are common and occur with a high degree of variability in male mice. In addition, mutagenicity studies conducted on quizalofop ethyl did not demonstrate evidence of mutagenic potential. Consequently, there is no concern for the carcinogenicity following exposure to quizalofop ethyl.

Specific information on the studies received and the nature of the adverse effects caused by quizalofop ethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Quizalofop-P-ethyl: Human Health Risk Assessment for New Uses on Sorghum, Rapeseed Crop Group 20 A, and Field Corn,” at pp. 33-34 in docket ID number EPA-HQ-OPP-2010-1018.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in



conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for quizalofop ethyl used for human risk assessment is shown in the Table of this unit.

**Table —Summary of Toxicological Doses and Endpoints for Quizalofop Ethyl for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	No appropriate endpoint was identified. There were no effects observed in oral toxicity studies that could be attributed to a single-dose exposure.		
Chronic dietary (All populations)	NOAEL = 0.9 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.009 mg/kg/day  cPAD = 0.009 mg/kg/day	Chronic toxicity/Carcinogenicity study in rats. LOAEL = 3.7 mg/kg/day based on increased incidence of centrilobular enlargement of the liver in both sexes and mild anemia in males.
Cancer (Oral, dermal, inhalation)	No concern as to human carcinogenicity.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. Mg/kg/day = milligrams/kilograms/day.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to quizalofop ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing quizalofop ethyl tolerances in 40 CFR 180.441. EPA assessed dietary exposures from quizalofop ethyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for quizalofop ethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA incorporated tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that there is no concern with regard to carcinogenicity. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is not needed.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for quizalofop ethyl. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for quizalofop ethyl in drinking water. These simulation models take into account data on the physical,

chemical, and fate/transport characteristics of quizalofop ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of quizalofop ethyl for chronic exposures for non-cancer assessments are estimated to be 2 parts per billion (ppb) for surface water and 1.29 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Quizalofop ethyl is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found quizalofop ethyl to share a common mechanism of toxicity with any other substances, and quizalofop ethyl does not appear to produce a toxic

metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that quizalofop ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The quizalofop ethyl toxicity database is adequate to evaluate potential increased susceptibility of infants and children, and includes developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. In developmental toxicity studies in rats and rabbits, maternal effects, including decreased body weight gains and food consumption, were noted (100 mg/kg/day for rats and 60 mg/kg/day for rabbits) in the absence of developmental effects. In the 2-generation reproduction study in rats, maternal effects (decreased body weight and body weight gains) were noted at 20 mg/kg/day, the same dose level that resulted in

prenatal and postnatal effects (decreased percentage of pups born alive and decreased pup weights).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for quizalofop ethyl is complete except for acute and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 imposed new data requirements for acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200) for pesticide registration. HED has determined from available studies in the quizalofop ethyl toxicity data base that quizalofop does not have specific neurotoxicity. More specifically, there were no treatment-related effects on brain weight or histopathology of the nervous system seen in studies that measured these endpoints. There was no evidence of effects on functional development observed in a postnatal segment of the reproduction study in rats. In addition, quizalofop ethyl does not belong to a chemical class that is considered neurotoxic. Although clinical signs possibly indicative of neurotoxicity were seen, they were only observed at high doses and, even then, were rare. The requested acute and subchronic neurotoxicity studies are expected to confirm that there are no indications of neurotoxicity. Therefore, EPA does not believe that conducting acute and subchronic neurotoxicity studies will result in a NOAEL less than the chronic NOAEL of 0.9 mg/kg/day already set for quizalofop ethyl. Based on the information in this unit, EPA has also determined that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

ii. There is no evidence that quizalofop ethyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The chronic dietary exposure assessments were performed based on 100 PCT and tolerance-level residues, and EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to quizalofop ethyl in drinking water. These assessments will not underestimate the exposure and risks posed by quizalofop ethyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, quizalofop ethyl is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to quizalofop ethyl from food and

water will utilize 29 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for quizalofop ethyl.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short- or intermediate-term adverse effect was identified, quizalofop ethyl is not expected to pose a short- or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* Based on the information described in Unit III.A., there is no concern for human carcinogenicity.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to quizalofop ethyl residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (Morse Method Meth-147, a high performance liquid chromatography method) is available to enforce the tolerance expression for plant commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for quizalofop ethyl.

### *C. Revisions to Petitioned-For Tolerances*

Based on analysis of the residue field trial data supporting the petitions, EPA revised the proposed tolerances on rapeseed subgroup 20A, except flax, seed from 1.0 ppm to 1.5 ppm; sorghum, grain, stover from 0.35 ppm to 0.30 ppm; crambe, meal from 1.5 ppm to 2.0 ppm; and gold of pleasure, meal from 1.5 ppm to 2.0 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

Based on available canola processing data, a tolerance for canola, meal was previously established at 1.5 ppm. Using the available canola processing data, EPA has recommended a tolerance for gold of pleasure, meal; and crambe, meal at 2.0 ppm, by adjusting for the proposed application rate. As such, the previously established tolerance on canola, meal at 1.5 ppm was also revised to 2.0 ppm, and EPA is revising the commodity definition for canola, meal to rapeseed, meal in order to reflect the correct



commodity terminology. Therefore, EPA determined that a tolerance should be established on rapeseed, meal at 2.0 ppm, and the established tolerance on canola, meal at 1.5 ppm should be removed.

The Agency also revised several other proposed and established commodity definitions to reflect the correct terminology, as follows: Bean, dry to bean, dry seed; sorghum, grain to sorghum, grain, grain; sorghum, forage to sorghum, grain, forage; sorghum, stover to sorghum, grain, stover; sorghum, aspirated grain to sorghum, grain, aspirated grain fractions; and soybean to soybean, seed.

## **V. Conclusion**

Therefore, tolerances are established for residues of quizalofop ethyl, ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate, in or on crambe, meal at 2.0 ppm; gold of pleasure, meal at 2.0 ppm; rapeseed, meal at 2.0 ppm; rapeseed, subgroup 20A, except flax, seed at 1.5 ppm; sorghum, grain, grain at 0.20 ppm; sorghum, grain, forage at 0.20 ppm; sorghum, grain, stover at 0.30 ppm; and sorghum, grain, aspirated grain fractions at 1.0 ppm. This final rule additionally removes the established tolerances for canola, seed at 1.0 ppm; and canola, meal at 1.5 ppm. This regulation also deletes time-limited tolerances for quizalofop ethyl on beet, sugar, molasses at 0.2 ppm; beet, sugar, roots at 0.1 ppm; beet, sugar, tops at 0.5 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 3.0 ppm; and vegetable, legume, group 6 at 0.25 ppm, as the tolerances expired on June 14, 1999. Finally, this final rule revises the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of quizalofop ethyl not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 11, 2012.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.441 is amended as follows:

- i. Revise paragraph (a)(1);
- ii. Revise paragraph (a)(2) introductory text;
- iii. Remove paragraphs (a)(3) and (a)(4); and
- iv. Revise paragraph (c) introductory text.

The revisions read as follows:

**§ 180.441 Quizalofop ethyl; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the herbicide quizalofop ethyl, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only those quizalofop ethyl residues convertible to 2-methoxy-6-chloroquinoxaline, expressed as the stoichiometric equivalent of quizalofop ethyl, in or on the commodity.

Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Bean, dry, seed	0.4
Bean, succulent	0.25
Beet, sugar, molasses	0.2
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Cotton, undelinted seed	0.1

Cowpea, forage	3.0
Cowpea, hay	3.0
Crambe, meal	2.0
Flax, seed	0.05
Gold of pleasure, meal	2.0
Lentil, seed	0.05
Pea, dry	0.25
Pea, field, hay	3.0
Pea, field, vines	3.0
Pea, succulent	0.3
Peppermint, tops	2.0
Rapeseed, meal	2.0
Rapeseed subgroup 20A, except flax, seed	1.5
Sorghum, grain, aspirated grain fractions	1.0
Sorghum, grain, forage	0.20
Sorghum, grain, grain	0.20
Sorghum, grain, stover	0.30
Soybean, flour	0.5
Soybean, hulls	0.02
Soybean, meal	0.5
Soybean, seed	0.05
Soybean, soapstock	1.0
Spearmint, tops	2.0
Sunflower, seed	1.9
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(2) Tolerances are established for residues of the herbicide quizalofop ethyl, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only those quizalofop ethyl residues convertible to quizalofop (2-[4-(6-chloroquinoxalin-2-yl-oxy)phenoxy]propanoic acid), expressed as quizalofop, in or on the commodity.

\* \* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of the herbicide quizalofop ethyl, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only those quizalofop ethyl residues convertible to 2-methoxy-6-chloroquinoxaline, expressed as the stoichiometric equivalent of quizalofop ethyl, in or on the commodity.

\* \* \* \*

[FR Doc. 2012-9447 Filed 04/19/2012 at 8:45 am; Publication Date: 04/20/2012]